REMARKS

Applicant respectfully requests reconsideration in view of the foregoing amendments and the following remarks. Claims 1-11 were previously pending. Claims 1-6 have been canceled as being drawn to a non-elected invention. Applicant reserves the right to file a divisional application to the subject matter of the canceled claims. Thus, claims 7-11 are pending for examination, with claim 7 being the sole independent claim. No new matter has been added.

Allowable Subject Matter

Applicant acknowledges the Examiner's indication that claims 8-11 recite allowable subject matter. The allowable claims have not been rewritten in independent form at this time because they depend from claim 7 which is believed to be allowable for reasons discussed further below.

Claim Rejections – 35 U.S.C. 103

Claim 7 stands rejected under 35 U.S.C. 103(a) as being unpatentable over Elgas et al. (EP 1086712 A2) in view of Shettigar (US 5,055,198). Applicant respectfully traverses this rejection.

Independent claim 7 is directed to an apparatus for extracorporeal oxygenation of a patient's blood during cardiopulmonary bypass surgery. The apparatus comprises, among other features, a bubble sensor that is arranged at or connected to a venous line to detect bubbles in the venous blood received from the patient, and an air filter that is connected to the venous line and arranged downstream of the bubble sensor to separate air for blood. The air filter includes an air chamber adapted to receive air and a diverter to divert the air entering the air filter into the air chamber. The apparatus also comprises a first pump to generate a first vacuum to pump blood through the venous line, the air filter, a blood oxygenator and an arterial line. The apparatus further comprises a second pump to generate a second vacuum to draw air from the air chamber of the air filter only when bubbles are detected in the venous blood by the bubble sensor.

Elgas is directed to an extracorporeal blood circuit that includes a venous line 14, a venous reservoir 16, an air sensor 22, a pump 17, an oxygenator 18 and an arterial line 20. (See FIG. 1). Elgas indicates that filtered and defoamed cardiotomy blood may be introduced into the venous reservoir 16 by appropriate equipment (not shown). (Col. 2, lines 42-44).

Recognizing that Elgas does not disclose a second pump to draw air from an air chamber of an air filter, the examiner looked to Shettigar as purportedly disclosing a pump for removing air bubbles from a filter. (Office Action, page 4). The examiner contended that it purportedly would have been obvious to one of ordinary skill in the art at the time of the invention to have provided the Elgas apparatus with a second pump, as purportedly taught by Shettigar, to provide active removal of air bubbles. Applicant respectfully disagrees.

Claim 7 patentably distinguishes over the combination of Elgas and Shettigar.

Without acceding to the propriety of the purported combination, even were Elgas and Shettigar properly combinable, claim 7 nevertheless patentably distinguishes over the references which fail to teach or suggest each feature of the claimed apparatus as recited in the claim.

As indicated above, claim 7 recites that the apparatus comprises a bubble sensor that is arranged at or connected to the venous line to detect bubbles in the venous blood received from the patient. The apparatus also comprises a second pump to generate a second vacuum to draw air from the air chamber of the air filter, which is connected to the venous line and arranged downstream of the bubble sensor, only when bubbles are detected in the venous blood by the bubble sensor.

In Elgas, the extracorporeal system employs an air sensor 22, which is located between the reservoir 16 and the pump 17, to shut down the pump and cease positive blood flow through the blood line 32 upon detection of air. (Col. 3, para. 0018 and col. 4, para. 0020). Elgas indicates that air boluses in the line of an extracorporeal circuit could lead to serious injury or death of a patient. (Col. 1, para. 0003). However, the air sensor has no controlling function for removing air from an air filter. Although Elgas indicates that filtered and defoamed cardiotomy blood may also be introduced into the reservoir, Elgas provides no description as to the equipment or process for carrying this out. (Col. 2, para. 0011).

Shettigar fails to cure the deficiencies of Elgas. Even were one of ordinary skill in the art to consider the emboli filter 18 of Shettigar to be an air filter that includes an air chamber to receive air and a diverter to divert air entering the air filter into the air chamber, the vacuum source 28 is not operated in conjunction with a bubble sensor. In this regard, Shettigar does not teach or suggest a bubble sensor that is located upstream of an air filter to detect air bubbles in the venous blood

received from a patient. Additionally, Shettigar does not teach or suggest an arrangement in which a pump generates a vacuum to draw air from an air filter only when bubbles are detected in the venous blood by a bubble sensor. Rather, Shettigar discloses the use of a bubble detector 58 that is located downstream of a membrane filter 38 and along the reinfusion pathway 50 of the autologous blood recycling apparatus. Shettigar employs the bubble detector 58 in conjunction with a blood level detector 60 and a conductivity monitor 42 to control opening a venous valve 54 in the reinfusion pathway only when three conditions are met simultaneously, including the lack of air bubbles in the reinfusion pathway. (Col. 10, lines 14-29).

In the Office Action, the examiner contended that Shettigar provides a system with active removal of air bubbles, as purportedly disclosed at col. 11, lines 32-33 of the reference. However, Applicant respectfully submits that this portion of Shettigar is not concerned with removal of air bubbles from blood. Rather, Shettigar discloses an arrangement for eliminating air suction into the membrane filter 38 during a washing cycle prior to operation of the system. In particular, the filtrate port 46 may be closed by a filtrate valve 62 which closes only when the fluid level in the reservoir 22 falls below the level of the blood level detector 60. (Col. 11, lines 30-37).

Moreover, Applicant respectfully submits that one of ordinary skill in the art would have had no apparent reason to modify the Shettigar system with a bubble sensor that is used in conjunction with the vacuum source 28. In this regard, the Shettigar system employs the vacuum source 28 to create suction at the suction means 12 for aspirating blood from a wound site and drawing the aspirated blood into the cardiotomy reservoir. (Col. 7, line 55 to col. 8, line 4). Controlling the vacuum source so that it would operate only when bubbles are detected in the venous blood would result in a system that does not aspirate blood from a wound site. Such a modification would render the Shettigar system unsatisfactory for its intended purpose and also change its principle of operation. This is impermissible.

In view of the foregoing, claim 7 patentably distinguishes over Elgas and Shettigar, taken either together or alone, which do not teach or suggest a system that includes a bubble sensor and a second pump for removing air bubbles from venous blood as recited in the claim. Accordingly, the rejection of claim 7 under §103 is improper and should be withdrawn.

CONCLUSION

In view of the foregoing remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this response, that the application is not in condition for allowance, the Examiner is requested to call the undersigned at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, please charge any necessary fee to Deposit Account No. 23/2825, under Order No. H0075.70113US00 from which the undersigned is authorized to draw.

Dated: 4/6/09

Respectfully submitted,

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